

### **REMARKS/ARGUMENTS**

This amendment is fully responsive to the final Office Action mailed July 9, 2008. With this amendment, claims 1 and 9 have been amended. Amendments to the as-filed claims are not made for reasons related to patentability, but instead are made solely to expedite prosecution of this case. No new matter has been entered. Claim 4 was previously cancelled, and claim 10 was previously withdrawn from consideration. Claims 1-3, 5-9, and 11 are currently pending in the application. Applicants respectfully request reconsideration of this application in light of the amendments and the remarks set forth below.

#### **Examiner Interview**

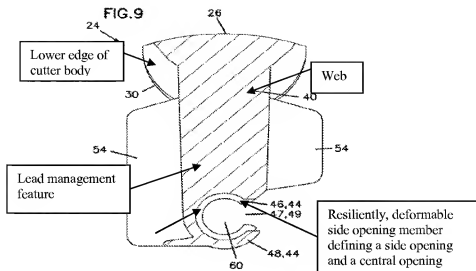
Applicants thank the Examiner for granting and participating in the interview on September 8, 2008. Amendments to the claims and the prior art references were discussed.

#### **Claim Rejection Under 35 U.S.C. § 103(a)**

Claims 1-3 and 9 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Brenner (US 6,497,681 B1).

Independent claim 1 is directed to a device for removing a guide catheter from about a linear object positioned within a lumen of the guide catheter. The device includes a distal lead management segment including a resiliently deformable side opening member defining a side opening and central opening sized to engage the linear object. The side opening has a first dimension smaller than a diameter of the linear object. Additionally, the side opening member is configured to be deformable away from the lower edge of the lead body to allow the lead to be snapped into the central opening, and further configured to retain the lead within the central opening.

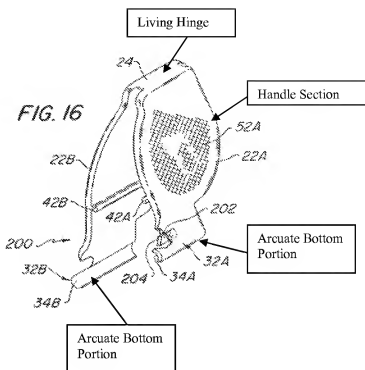
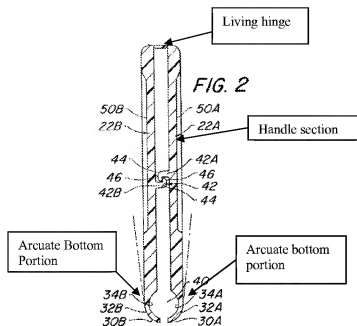
Additionally, the device as recited by claim 1 includes a web extending from a lower edge of the body. The web includes an upper portion and a lower portion. The distal lead management segment is connected directly to the lower portion of the web opposite the lower edge of the body such that the web extends directly from the lower edge of the body to the distal lead management segment. Independent claim 9 recites similar structural features. See for example, FIG. 9 reproduced below.



Applicants disagree with the Office Action's interpretation of the Brenner device. Additionally, it appears that the rejection is attempting to rearrange the parts of the Brenner device to meet the terms of claims 1 and 9. This is not sufficient to support a finding of obviousness. Brenner must provide a motivation or reason, without the benefit of the instant specification, to make the necessary changes in the Brenner device to meet the features of the claimed invention. (MPEP 2144.044 Section VI (C)).

The rejection asserts that Brenner discloses a distal lead management segment including a side opening member, and that the side opening member is "configured to deform, change shape from an open to a closed configuration, to snap and secure the object into place." (p. 3 of the Final Office Action mailed 7/9/08). Additionally, the rejection asserts that closing the side opening around the linear lead to secure the linear lead "comprises snapping the side opening around the linear lead." (p. 3 of the Final Office Action mailed 7/9/08).

In contrast to the claimed invention, Brenner is directed to a device including two handle sections 22A, 22B connected together by a living hinge 24 located at the top of the device such that their respective arcuate bottom portions 32A, 32B form a pair of jaws or pinchers capable of gripping a lead body (col. 5, lines 60-65). See for example, FIGS. 1A and 16 reproduced below.



When the device's two handle sections 22A and 22B are brought into a confronting relationship via the living hinge, the jaws 32A or 32B are opposed to each other and form an open tubular channel between their respective inner surfaces. An external force must be applied in order for the *two jaws* to engage the lead in the channel. Additionally, Brenner teaches that the inner diameter of the channel, *is slightly larger* than the outer diameter of the pacing lead. The pacing lead will be surrounded by those jaws, but not tightly engaged by the inner surfaces. (col. 5, line 66 - col. 6, line 10) The user squeezes the two handle sections together to frictionally grasp the lead in the channel formed by the jaws. (col. 6, lines 16-20).

Brenner does not teach a side opening member defining a side opening having a first dimension smaller than a diameter of the linear object, as recited by claimed invention. Additionally, by teaching that the channel has a slightly larger diameter than the pacing lead and that the lead is not tightly engaged by the inner surfaces, Brenner teaches away from the side opening as recited by claims 1 and 9 of the present invention.

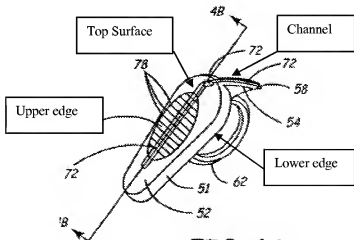
Brenner, as interpreted by the Office Action, teaches that the jaws (32a or 32b) are capable of deforming from a closed position to an open position via the living hinge located at the upper edge of the body of the device. As such, Brenner cannot teach a device

including a web and a resiliently deformable side opening member as recited by claims 1 and 9 of the present invention. Brenner teaches that the handles 22A, 22B must move via the living hinge 24 in order to transition the two arcuate portions 32A, 32B from an open to a closed position. The deformable side opening member, as interpreted by the Office Action, must include the handle in order to deform and thus, cannot be connected to the body of the device by a web as recited by the instantly claimed invention.

Brenner fails to teach or suggest each and every limitation of claim 1 and 9 and as such fails to render obvious the claimed invention. Dependent claims 2-3 are also patentable over Brenner for at least those same reasons as discussed above. Withdrawal of the rejection is respectfully requested.

Claims 1-3, 5-9 and 11 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Gardeski et al. (US 2003/0181935).

Gardeski is directed to a slitting tool having including a top surface 52 having a channel 72 that extends along at least a portion of the top surface 52 and further continues along at least a portion of front surface 54 of the nose 53 (paragraph [0047]). A user's thumb is placed over the lead placed in the channel 72 to retain the lead within the channel 72. See for example FIG. 4A, reproduced on the next page.



Applicants disagree with the Office Action's interpretation of the Gardeski device, as the Gardeski device is structurally dissimilar from the device of the instantly claimed

invention. Additionally, it appears that the rejection is attempting to rearrange the parts of the Gardeski device to meet the terms of claims 1 and 9. This is not sufficient to support a finding of obviousness. Gardeski must provide a motivation or reason, without the benefit of the instant specification, to make the necessary changes in the Gardeski device. (MPEP 2144.044 Section VI (C)).

The channel 72, as taught by Gardeski, is *formed in the top surface* of the slitting tool. Gardeski does not teach that the channel 72 is connected directly to the lower portion of a web opposite the lower edge of the body such that the web extends directly from the lower edge of the body to the channel 72, as recited by claims 1 and 9. Additionally, Gardeski does not teach that the channel 72 includes a side opening having a first dimension smaller than a diameter lead body.

Further, Gardeski does not teach or suggest the channel 72 is resiliently deformable nor does Gardeski teach or suggest that the channel is configured to be deformable to allow the lead to be snapped into the central opening, as recited by claims 1 and 9.

Gardeski teaches that “because of the size of the channel, *only a portion of the lead 90 resides within the channel 72.*” (paragraph [0050]). External pressure must be applied to the lead in order to retain the lead within the channel 72. For example, Gardeski teaches that “a thumb 92 of a user may be placed over the lead with pressure applied in a downward direction. This force maintains the lead 90 against the top surface 52 within recessed area 70.” (paragraph [0050]). Without the application of the external pressure, the channel 72 alone is not capable of retaining the lead.

In an alternative embodiment, Gardeski discloses that in one region, the channel may be deep enough to receive the entire body of the lead 90. However, a finger is still required to be positioned within the recessed area. (paragraph [0051]) Thus, even though the channel 72 is deep enough to receive the lead, it still is not capable of engaging the lead therein without the application of external pressure.

In requiring a finger to be placed over the lead in order to retain the lead within the channel, Gardeski teaches away from the device of the claimed invention including a side opening having a first dimension smaller than a diameter of the lead. A side opening member including a side opening having a first dimension smaller than a diameter of the lead

is capable of retaining the lead within the central opening without the application of a finger or other external force placed on the lead.

Additionally, the rejection asserts that Gardeski discloses that the central opening and side opening member is comprised of a low durometer polymer. Gardeski teaches that a low durometer polymer is used to provide an overmolding material to provide a tacky channel surface to minimize relative movement of the slitting tool to the axis of the lead body or delivery sheath. (paragraph [0059]). Gardeski does not teach or suggest that the low durometer of the polymer allows the lead to be *snapped into* the central opening. At most, Gardeski suggests that a low durometer polymer provides tacky surface characteristics. Further, Gardeski teaches away from a resiliently deformable opening that allows a lead to be snapped into the opening as Gardeski consistently requires the application of external pressure via a user's thumb to retain the lead within the opening.

Gardeski fails to teach or suggest each and every limitation of claims 1 and 9 and as such fails to render obvious the claimed invention. Dependent claims 2-3, 5-8, and 11 are also patentable over Gardeski for at least those same reasons as discussed above. Withdrawal of the rejection is respectfully requested.

### **Conclusion**

All of the pending claims are in condition for allowance. A prompt notice to that effect is respectfully solicited. If there are any remaining questions, the Examiner is requested to contact the undersigned at the number listed below.

Respectfully submitted,

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